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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/031,531      | 04/15/2002  | Neil R. Anderson     | 29342/36231'A       | 6194             |

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EXAMINER

TRAN, SUSAN T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 06/12/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/031,531

Applicant(s)

ANDERSON ET AL.

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 & 8.      6) ☐ Other: .

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Declaration and Amendment filed 04/15/02, Information Disclosure Statement filed 05/16/02, and Supplemental Information Disclosure Statement filed 03/06/03.

#### ***Claim Objections***

Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "about 3% to about 8% by weight propylene glycol, and about 90% to about 95% by weight polyethylene glycol 400" in lines 3-5. There is insufficient antecedent basis for this limitation in the claim. Claims 1 and 2 do not recite the limitation.

Claim 15 recites the limitation "about 5% to about 8% by weight propylene glycol, about 10% to 60% by weight of C<sub>8</sub>-C<sub>10</sub> monoglycerides, and about 30% to about 75%

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by weight polyglycolized glyceride" in lines 3-7. There is insufficient antecedent basis for this limitation in the claim. Claims 1-3 do not recite the limitation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Daugan WO 97/03675.

Daugan teaches orally administering an active compound of formula (I) for the treatment of sexual dysfunction (pages 2-4). The active compound is administered in the form of capsule in an amount of 0.5 to 500 mg daily (page 5, 1<sup>st</sup> paragraph). The active compound can be in the form of elixirs, liquid, or suspensions; and contains diluents, excipients, carriers, and suspending agent (page 5). Page 15 discloses a capsule formulation comprises active ingredient, polyvinyl pyrrolidone, and magnesium stearate.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 10, 14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan WO 97/03675.

Daugan is relied upon for the reason stated above. In the case that applicant can overcome the above 102(b) rejection, it is the position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation optimize the use of the active compound in view of the teaching of Daugan to obtain the claimed invention, because the reference teaches the advantageous results in the use of the same compound in a similar oral formulation for the same treatment, *e.g.*, sexual dysfunction.

Claims 1, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan WO 97/03675, in view of Wyllie WO 99/30697.

Daugan is relied upon for the reasons stated above. Daugan does not teach the claimed solvent as recites in claims 7 and 11.

Wyllie teaches the use of the same active compound (formula I) for oral administration in the form of aqueous suspension, elixirs, and capsule (page 17). The formulation further comprises polyvinyl pyrrolidone, and polyethylene glycol (page 17). Thus, it would have been obvious for one of ordinary skill in the art to modify the formulation of Daugan using the solvent in view of the teaching of Wyllie with the expectation of at least similar result, because the references teach the advantageous

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results in the use of the claimed compound in a similar oral formulation for the same treatment, e.g., sexual dysfunction.

### ***Claims Objection***

Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allemeier et al., and Pullman et al. are cited as being of interest for the teachings of methods of treating sexual dysfunction.

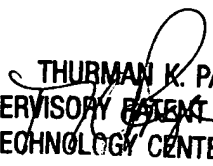
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600